REMARKS

Claims 1-38 are pending in this application with claims 1-18 and 22-38 currently being withdrawn from examination. As a result, claims 19-21 are pending for examination with claim 19 being the sole independent claim. No new matter has been added.

Amendments to the Specification

In response to the objection of the specification, Applicants have amended the Abstract. Therefore, it is believed that the objection to the specification has been overcome.

Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 19-21 under 35 U.S.C. § 103(a) as being unpatentable over Medlen (WO 85/00511) in view of Bell (6,153,292) and MacPhee (6,117,425). To support these rejections, the Examiner states that Medlen, Bell, and MacPhee may be combined and that MacPhee discloses a method using a composition including platelets to treat an intra-articular injury in a subject as claimed in claim 19. Applicants respectfully traverse these rejections as follows.

Even if combined in the manner suggested by the Examiner, the combination is missing at least one of the claimed elements. Specifically, Medlen in view of Bell and MacPhee does not teach or suggest the features of claim 19, including contacting the ends of a ruptured tissue from the subject with a composition comprising soluble type 1 collagen, a platelet, and at least one of an extracellular protein and a neutralizing agent. As noted by the Examiner, Medlen and Bell do not disclose or suggest using a platelet in a repair composition. The Examiner turns to MacPhee to cure this deficiency. Applicants respectfully traverse the Examiner's contention that MacPhee discloses a tissue repair implant including platelets to induce healing.

To show the addition of platelets to tissue repair implants, the Examiner specifically points to column 12, lines 13-18 and column 23, lines 32-40 of MacPhee. Upon review of these specific sections, as well as MacPhee as a whole, Applicants are unable to find any reference of the addition of *platelets* to any type of tissue sealant. Rather, MacPhee is directed to adding an effective amount of a platelet-derived extract such as platelet-derived growth factor or platelet-derived wound healing factor. These derivative growth factors, although derived from platelets, do not teach or suggest that the platelets themselves may be added to tissue sealants, much less

tissue repair implants. Thus, it is apparent that even if combined, Medlen in view of Bell and MacPhee does not disclose or suggest the features of claim 19 including contacting the ends of a ruptured tissue from the subject with a composition comprising soluble type 1 collagen, a platelet, and at least one of an extracellular protein and a neutralizing agent.

The Examiner also suggests the desirability of modifying or combining the invention of Medlen with both Bell and MacPhee. However, MacPhee teaches away from a combination with Medlen or Bell. More particularly, MacPhee specifically notes that the tissue sealants disclosed should only contain proteins of human origin noting that the risks of allergic reactions, and bovine spongiform encephalopathy are not insignificant concerns. (MacPhee, Col. 4, lines 51-67; col. 13, lines 17-26). In contrast, the collagen implant of Medlen utilizes bovine skin collagen which may be woven to produce the needed collagen implant. Similarly, Bell suggests that its source of biopolymers includes mammals such as pigs, sheep, and cows. (Bell, column 5, lines 21-22). Thus, those skilled in the art would have no motivation to combine or modify the teachings of Medlen or Bell in view of MacPhee, since MacPhee suggests that non-human components such as collagen or protein should not be used. See Winner International Royalty Corp., 202 F.3d at 1350 ("Johnson taught away from Moore, and therefore was not shown to be combinable with Moore."); Tech Air, Inc. v. Denso Manufacturing Michigan, Inc., 1932 F.3d 1353, 1360 (Fed. Cir. 1999) ("There is no suggestion to combine ... if a reference teaches away from its combination with another source.").

Moreover, Applicants disagree with the Examiner that these references can or should be combined. Initially, the implant disclosed in Medlen is attached to the ruptured ends of a ligament *in vivo*, whereas the ligament repair disclosed in Bell is conducted *in vitro*. There is no teaching or suggestion in either Bell or Medlen to suggest that the *in vitro* method or implant components of Bell may be combined with or modified for *in vivo* repair of ligament tissue as in Medlen.

Furthermore, the Examiner has not provided a motivation to combine Medlen with both Bell and MacPhee. Regardless of whether it may be possible to modify or combine Medlen in view of Bell and/or MacPhee, a motivation to combine or modify requires a teaching that such combination is clear and particular and desirable. See Winner International Royalty Corp. v. Wang, 202 F.3d 1340 (Fed. Cir. 2000) (at text accompanying footnote 8); In re Dembiczak, 175 F.3d 994, 999, (Fed. Cir. 1999). The stated motivation: "to provide a more natural implant" is a

non-specific, hindsight rationale clearly based on Applicants' own disclosure, and is entirely inadequate under the law. See Dembiczak, 175 F.3d at 999 ("Broad conclusory statements regarding the teaching in multiple references standing alone, are not "evidence" "of a motivation to combine references."); In re Fritch, 972 F.2d 1260, 1265 (Fed. Cir. 1992) ("It is impermissible to use the claimed invention as the instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious"). The fact that Medlen, Bell, and MacPhee are three of hundreds of patents related to the broad area of medical implants does not provide any teaching, suggestion, or motivation to combine the references. Each reference accomplishes its intended task and is complete within its own specification.

For at least the foregoing reasons, Applicants maintain that independent claim 19 is patentable over Medlen in view of Bell and MacPhee, either alone or in combination. Dependent claims 20-21 depend from independent claim 19, and for at least the reasons set forth above, these claims are patentable over Medlen in view of Bell and MacPhee. Accordingly, withdrawal of this rejection is respectfully requested.

The Office Action also rejected claims 19 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Li (WO 93/21857) in view of MacPhee. Applicants respectfully traverse the rejection as follows.

Even if combined, the cited references of Li and MacPhee, either alone or in combination, do not teach or suggest the features of claim 19, including contacting the ends of a ruptured tissue from the subject with a composition comprising soluble type 1 collagen, a platelet, and at least one of an extracellular protein and a neutralizing agent. In contrast, Li is directed to a total replacement ligament formed from collagen. Thus, the Li reference does not teach or suggest contacting the ends of ruptured tissues as recited in claim 19. Rather, Li completely replaces ruptured ligament tissue, i.e., attaches the implanted collagen braid from bone to bone. Moreover, as noted by the Examiner, the Li reference additionally does not disclose using a platelet in the implant material. However, for the reasons noted above, MacPhee does not cure this defect in Li as suggested by the Examiner. Thus, Li in view of Macphee does not teach or suggest contacting the ends of a ruptured tissue from the subject with a composition comprising soluble type 1 collagen, a platelet, and at least one of an extracellular protein and a neutralizing agent as recited in claim 19.

For at least the foregoing reasons, Applicants maintain that independent claim 19 is patentable over Li in view of MacPhee, either alone or in combination. Dependent claim 20 depends from independent claim 19, and for at least the reasons set forth above, is also patentable over Li in view of MacPhee. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

Martha M. Murray, M.D., et al., Applicants

By: _____

Carole A. Boelitz, Reg. No. 48,958
Helen C. Lockhart, Ph.D., Reg. No. 39,248
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

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MARKED-UP ABSTRACT

The invention provides [composition] compositions and methods for repairing [ruptured anterior cruciate ligament.] intra-articular and extra-articular tissue including ligament, meniscus, cartilage, tendon, and bone. The method includes contacting the ends of an injured tissue from a patient with a composition. The repair composition includes soluble type 1 collagen, a platelet, and at least one of an extracellular protein and a neutralizing agent.